REMARKS

Claims 13 and 17-19 have been amended, and claim 21 added. Thus, claims 13-21 are pending. Counsel for the Applicants thanks Examiner Weiss for the courtesy extended during the phone conference of November 12, 2002. As a result of the phone conference, a better understanding of the Examiner's interpretation of the cited Dryden reference was obtained, which facilitated the preparation of this response establishing that the Dryden reference does not teach or suggest the claimed inventions, and in fact teaches away.

Drawings: It is respectfully submitted that the filter located in the proximal fitting recited in claims 15 & 16 is shown *inter alia* in Figure 4, part 90, Figures 6A & 6B, parts 158 and 168, Figure 11, part 190, and Figure 22, part 360. It is respectfully noted that the specification teaches that a multilumen filter of the present invention may be used as a multilumen proximal fitting, see for example page 12, lines 18-24, and page 34, lines 2-6. Therefore, it is requested that the objection to the drawings be withdrawn.

Specification: It is respectfully submitted that this objection should be withdrawn for the same reason as the objection to the drawings set forth above.

Claim Rejections:

35 USC §112

It is respectfully submitted that the rejection of claims 15 & 16 should be withdrawn for the same reason as the objection to the drawings set forth above.

It is respectfully submitted that the amendments to claims 13 and 19 overcome the remaining rejections under 35 USC §112.

35 USC §102(e)

Claims 13-14 and 17-20 are rejected over U.S. Patent 5,284,160, to Dryden.

Rejection Clarified

During the phone conference of November 12, 2002, the Examiner explained that the rejection was based on the Examiner's speculation that Dryden's swivels, such as 35a, 35b, 85A, and 85 B, could possibly be formed and deformed by a user at a site of use to assemble and disassemble the breathing circuit of Dryden. The Examiner indicated a willingness to withdraw the rejection if it could be shown that one of ordinary

skill in the art would not interpret Dryden as inherently teaching or suggesting same. It was agreed that Dryden does not explicitly teach such a possibility. Further, the Examiner indicated the rejection could also be overcome by a showing that Dryden was not an enabling teaching, and/or that the device described and illustrated in Dryden was inoperative.

Dryden Teaches Away From the Claimed Inventions

It is respectfully submitted that the Dryden patent does not teach or suggest that the swivels could be pried apart in the circuit by a user at the site of use, and in fact teaches away from such an interpretation by teaching that the sampling tube is fixedly bonded in the proximal part of the connector by a solvent seal (col. 5, lines 18-19). The swivels are included in the Dryden device specifically because it is a unitary circuit with parts bonded together "by use of a solvent seal," as taught for example at column 5, lines 34-39. In the absence of the swivels in the machine adapter, twisting of the gas conduits could lead to kinking and blockages as the conduits are bonded to the machine adapter. Such obstruction could cause hypoxia to a patient, leading to death or serious harm. In the alternative, such twisting or tension could lead to unintended and undetected disconnection of the circuit during use, a highly undesired result. That such disconnection is undesirable is well known in the art from use of the devices referred to in column 1 of Dryden, such as U.S. Patent No. 3,856,051 to Bain, and from the patents considered in the Dryden prosecution and listed on its cover page, such as Fukunaga 4,265,235.

Further, the device illustrated in Dryden's Figure 1 is inoperative and as there is no mechanism taught or suggested by Dryden for connecting the device of Figure 1 to the separate and spaced apart inspiratory and expiratory ports of an anesthesia machine, such as those shown in Figure 11. In other words, Dryden's Figure 1 does not show a proximal terminal as defined in the present application because it does not provide for independent and spaced apart inspiratory and expiratory gas ports on the machine side that converge at the distal end to connect to the proximal ends of lumens of a proximal fitting and diverge at the proximal side to connect to the machine's separate ports. Hence the embodiment of Figure 1 is not operative and there is no enabling teaching of a use of the device in Figure 1. As is clearly shown in Figures 8

and 11 of Dryden, his circuit is unitary, and comprises only tubing bondedly connected to a machine adaptor.

Dryden teaches away from replacing the adaptor with a multilumen proximal fitting and mating multilumen proximal terminal, wherein the proximal fitting can be attached and detached by a user at a site of use to the proximal terminal, since disassembly of Dryden's adaptors would create an unsafe device that could not readily be reconnected in a safe fashion with substantially fluid tight seals between components.

In this regard, one of ordinary skill in the art of constructing respiratory circuits would be aware of industry guidelines and standards, for example applicable ISO standards, such as ISO 5356-1, attached and submitted with the attached Information Disclosure Statement. These standards call for attachable/detachable tubular connections to have smooth tapered fittings, not the interlocking bent flanges of Dryden's swivels. Clearly, one of skill in the art would not consider the components forming the swivels of Dryden to be designed for forming the swivel connection and destroying the swivel connection at the site of use, particularly considering the rushed, crowded, and life and death circumstances usually surrounding the use of respiratory circuits and existing standards. In other words, the swivel connection would be interpreted by one of ordinary skill in the art to be designed for its swiveling function, not for disconnection and reconnection. Trying to assemble and disassemble the swivel connections is simply not medically, much less, technically feasible.

<u>One of Skill in the Art Would Interpret Dryden to Teach a Unitary Bonded Circuit</u>

Applicants' current application introduces to the respiratory circuit art the concept of a multilumen proximal fitting for use with a multilumen proximal terminal, wherein the proximal fitting can be attached and detached from the proximal terminal by a user at the site of use for independent sterilization and/or disposal. The proximal fitting and proximal terminal are defined in Applicants' specification, e.g., see paragraph bridging pages 7 & 8, first full paragraph of page 13, and pages 19-23. The present inventions provide significant and unexpected improvements over prior art unilimb circuits, such as improved safety with reduced manufacturing and respiratory care/anesthesia costs. The prior art does not teach or suggest a multilumen proximal fitting, and teaches away

from making an independent proximal terminal which could take advantage of the proximal fitting of the present invention. Thus, the prior art would lead one of ordinary skill in the art to interpret Dryden to teach a unitary bonded circuit.

Examples of prior art patents that teach away from an independent proximal terminal in multilumen unilimb breathing circuits include U.S. Patent 3,856,051, U.S. Patent 4,007,737, and U.S. Patent 4,265,235 (to Dr. Atsuo Fukunaga, the present inventor), and U.S. Patent 4,637,384, all of which are cited on the cover of the cited Dryden patent. These patents contain numerous teachings of why it was considered necessary to firmly adhere the flexible patient respiratory conduits to the machine adaptor, wherein the entire circuit, tubing and machine adaptor bonded thereto, is disposed of after use. For example, U.S. Patent 4,367,769, to Bain, at column 1, lines 23-37, states:

> It is the fact of this connection [i.e., machine adaptor or proximal terminal] that has proved to be a considerable problem...The second flexible tube [i.e., fresh gas carrying inner tube] connected to the elbow has on occasion become disengaged whereby the anesthetic gas spills into the confines of the first flexible tubular member [i.e., the outer tube] to the detriment of the patient. Due to the fact that the connection to the elbow with the second flexible tubular member is internally with respect to the rigid tubular connector, one cannot visually inspect the device to determine whether the aforementioned internal connection is still in engagement.

Therefore, those of skill in art concluded that it was necessary to carefully bond all of the components of a respiratory circuit together, i.e., the machine adaptor was bonded to the flexible conduits running to the patient.

U.S. Patent 4,637,384, to Schroeder, column 1, lines 23-37, states:

> One difficulty with the coaxial circuit, particularly in anesthesia breathing circuits, is the assurance of the integrity of the inhalation circuit. Since the inner tube carries fresh gas to the patient or, in the case of an anesthesia circuit, the anesthetic with fresh gas, it is extremely important for the attending personnel to be immediately aware of an inadvertent disconnection.
>
> At the machine end, a disconnection of the inner tube can escape immediate attention, since its view is shielded by the surrounding corrugated outer tube. Thus, it is possible for the inner tube to be disconnected, yet the overall coaxial circuit has the appearance of being completely intact. The potentially dangerous situation of rebreathing

exhaled gases is created, which can result in hypoxia and CO_2 buildup in the patient.

Other prior art teachings reinforced the concept that respiratory conduits need to be firmly connected in a circuit. For example, Hannallah et al, assigned reference number A49 in the Information Disclosure Statement submitted August 15, 2002, reported the hazards associated with disconnection of the respiratory conduit from the machine end connector.

In view of the foregoing, it would be unreasonable for one of skill in the art to interpret Dryden to teach anything but a unitary bonded circuit, as (1) Dryden is directed to a circuit with a sampling tube BONDED into its machine adaptor, wherein the purpose of Dryden's swivels is to avoid twisting of the flexible conduits due to the permanent connection of the circuit components together, and (2) the prior art cited in the Dryden patent teaches the danger of detachment of circuit components. There is nothing in Dryden to teach or suggest forming and breaking the connection formed by the swivels, much less how one could do this in a fashion to maintain circuit integrity. It is difficult to imagine how an inner swivel, such as 35B, could be formed by a user at a site of use in view of the spacers 22G and 22H barring access to fingers and/or tools; certainly, there is no teaching or suggestion of such a formation technique or tools because Dryden's circuits are intended to be kept in one piece, and disposed of as one piece after use.

It was not until the present inventions were invented and publicized that those of skill in the art recognized the substantial benefits of a unilimb multilumen proximal fitting that is attachable and detachable to a mating multilumen proximal terminal, such as improved safety with a simpler and less expensive device. As seen from the prior art, including that cited in the Dryden patent, prior to the present invention, it was believed that detachability of the respiratory conduits from the rest of the circuit was extremely unsafe. The substantial benefits of the present inventions and the associated commercial success demonstrate that one of ordinary skill in the art could not reasonably interpret the Dryden patent as suggested in the office action.

Therefore, it is respectfully requested that the rejections based on Dryden be withdrawn.

35 USC §103(a)

Claim 20 is rejected over Dryden. Claims 15 and 16 are rejected over Dryden in view of U.S. Patent 5,715,815 to Lorenzen ("Lorenzen"). It is respectfully submitted that these rejections are moot in view of the arguments above. Further, Lorenzen does not solve the deficiencies of Dryden as it does not teach placement of a filter in the proximal fitting of a detachable breathing circuit, nor placement of a filter in both the inspiratory and expiratory lumens. In view of the forgoing, withdrawal of these rejections is respectfully requested.

Double Patenting

Claim 18 is rejected under the judicially created doctrine of obviousness-type double patenting as being obvious over claims 1-6 in U.S. Patent 5,778,872. Claims 13-17 and 19-20 are rejected on the same basis over claims 1-6 in U.S. Patent 5,778,872 and claims 1-20 in U.S. Patent 6,003,511. Terminal disclaimers are submitted herewith to overcome this rejection.

Further, in an effort to expedite prosecution, a Terminal Disclaimer over co-pending Serial No. 09/820,486, filed March 28, 2001, is also submitted herewith.

In view of the foregoing, it is respectfully submitted that all bases for rejection have been overcome, and allowance of claims 13-21 is respectfully requested. It is respectfully requested that the Examiner telephone the undersigned with any questions or concerns about the application so that further prosecution can be expedited.

Respectfully submitted,

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APPENDIX

Below are the amended claims with insertions underlined and deletions in brackets.

13. (amended) A multilumen proximal fitting for operatively connecting a multilumen patient respiratory conduit to a proximal terminal of an assisted ventilation or anesthesia machine, comprising a multilumen proximal fitting for connecting a unilimb multilumen respiratory conduit to a mating multilumen proximal terminal of an assisted ventilation or anesthesia machine, said fitting comprising a rigid housing forming at least two independent lumens, said lumens comprising a first lumen and a second lumen each having a proximal and a distal end, wherein said fitting may be operatively attached to a multilumen proximal terminal having first and second ports at the distal end of third and fourth lumens so that, when said [distal] proximal ends of said first and second lumens of said fitting are operatively attached to said first and second ports respectively the third lumen and said first lumen both form part of a first flow path that is independent of a second flow path that is formed at least in part by said second lumen and the fourth lumen, wherein said fitting is operatively attachable to and detachable from a mating multilumen proximal terminal [to which it is attachable] by a user at a site of use.

17. (amended) The fitting of claim 13, wherein said first and second lumens terminate at third and fourth distal ports and fifth and sixth proximal ports, wherein said fifth and sixth proximal ports are co-axial.

18. (amended) A unilimb respiratory conduit for providing inspiratory gases to a patient and receiving expiratory gases therefrom, [said] comprising a unilimb respiratory conduit for use with a proximal terminal that has lumens defining inspiratory and expiratory flow paths that are independent of each other and converge at a distal end of the proximal terminal and diverge from each other proximally of the distal end of the proximal terminal so that the lumen defining the inspiratory flow path of the proximal terminal is independently operatively connectable to an inlet for a source of inspiratory gas while the lumen defining the expiratory flow path of the proximal terminal is

independently operatively connectable to an expiratory outlet, said respiratory conduit comprising:

a first lumen and a second lumen, said first and second lumens forming independent flow paths, said respiratory conduit having a distal end and a proximal end, wherein said distal end of said respiratory conduit is operatively connectable to and detachable from a patient by a user at a site of use, and said proximal end of said conduit is operatively connectable to and detachable from a proximal terminal by a user at a site of use,

wherein when said conduit is operatively connected to a proximal terminal, said first lumen is in fluid communication with the inspiratory flow path and said second lumen is in fluid communication with the expiratory flow path, wherein said first lumen is operatively connectable to an inlet for a source of inspiratory gas via the proximal terminal while said second lumen is operatively connectable to an expiratory outlet via the proximal terminal, wherein said respiratory conduit is operatively attachable to and detachable from a proximal terminal after use therewith for independent disposal or sterilization by a user at the site of use.

19. (amended) A respiratory conduit interface device [for] capable of operatively coupling [a] the unilimb, multilumen flexible respiratory conduit of [the type described in] claim 18 to an anesthesia machine or respirator type device, comprising a rigid housing having first and second lumens defining respectively first and second flow paths therein, said first and second lumens being independent of each other and each having a distal end and a proximal end, said distal ends of said independent lumens converging at a distal end of said housing so as to be capable of simultaneous operative connection to a unilimb flexible respiratory conduit, and wherein said first and second flow paths in said housing diverge from each other proximally of said distal end of said housing so that said proximal end of said first lumen is independently operatively connectable to an inlet for a source of inspiratory gas while said proximal end of said second lumen is independently operatively connectable to an expiratory outlet, wherein a unilimb flexible respiratory conduit is operatively attachable to said housing for use and detachable therefrom after use for independent disposal or sterilization.